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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,987	10/12/2001	Raymond Clarke	10621-3	4161

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Sheldon & Mak
9th Floor
225 South Lake Avenue
Pasadena, CA 91101

EXAMINER
RHEE, JANE J

ART UNIT	PAPER NUMBER
1772	7

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-7

Office Action Summary	Application No.	Applicant(s)	
	09/976,987	CLARKE ET AL.	
	Examiner	Art Unit	
	Jane J Rhee	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11,13,15,16,20-26 and 28-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,13,15-16,20-26, and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1 and 20 are rejected under 35 U.S.C. 112, any negative limitation or exclusionary proviso must have basis in the original disclosure, the negative limitation set forth is "subject to the proviso that the polymeric coating does not comprise a crystalline polymer having a peak melting temperature Tp of –5 to 40°C, an onset of melting temperature To such that (Tp-To) is less that 10°C and a heat of fusion of at least 5 J/g".. If alternative elements are positively recited in the specification they may be explicitly excluded in the claims. See in re Johnson, 558 F.2d 1008/, 1019, 194 USPQ 187, 196 (CCPA 1977). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support. Ex parte Parks, 30 USPQ2d 1234, 1236 (bd. Pat. App. & Inter. 1993).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-4,6-8,14-16 are rejected under the judicially created doctrine of double patenting over claims 1-16 of U. S. Patent No. 6376032 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: A gas permeable membrane which is useful in the packaging respiring biological materials and which comprises a microporous polymeric film comprising a network of interconnected pores such that gases can pass through the film, and a coating on the microporous film wherein the polymeric coating has a thickness such that the membrane has a P_{10} ratio, over 10°C range between –5 and 15°C of at least 1.3; has a oxygen permeability (OTR), at all temperatures between 20°C and 25°C, of at least 775,000 ml/m^2.atm.24hrs (50,000cc/100 $inch^2$.atm.24hrs.) and has a CO_2/O_2 permeability ratio (R) of at least 1.5; the P_{10}, OTR, and R values being measured at a pressure of 0.035kg/cm^2 (0.5psi). A membrane wherein the microporous film comprises a polymeric matrix selected form the group consisting of an

essentially linear ultrahigh molecular weight polyethylene having an intrinsic viscosity of at least 18 deciliters/g and an essentially linear ultrahigh molecular weight polypropylene having an intrinsic viscosity of at least 6 deciliters/g. A membrane wherein at least 70% of the pores in the microporous film have a pore size of less then 0.24 micron. A membrane wherein at least 90% of the pores in the microporous film have a pore size of less than 0.24 micron. A membrane wherein at least 80% of the pores in the microporous film have a pore size less than 0.15 micron and at least 70% of the pores have a pore size less than 0.11 micron. A membrane which as an OTR of at least 1,550,000 ml/m^2.atm.24hrs (100,000cc/$inch^2$.atm.24hrs), and an R ratio of at least 2, the OTR and R values being measured at a pressure of 0.7 kg/cm^2 (10psi). A membrane which has an OTR of at least 2,325,000 ml/m^2.atm.24hrs (150,000cc/100$inch^2$.atm.24hrs) at a pressure of 0.7 kg/cm^2 (10psi). A membrane wherein the microporous polymeric film contains pores which are partially blocked by a polymer having an R ratio of leas than 1.3 or by a particulate material, or (b) has an OTR before coating of less than 15,500,000 (1,000,000). A package which is stored in air and which comprises a seal container, and within the sealed container, a respiring biological material and a packaging atmosphere around the biological material; the sealed container including one or more permeable control sections which provide at least the principal pathway for oxygen and carbon dioxide to enter or leave the packaging atmosphere, at least one of the permeable control section being gas permeable membrane.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

It is the examiner's position that the gas permeable membrane of US patent 6,376,032 is identical to or only slightly different than the gas permeable membrane prepared by the method of the claim(s), because both gas permeable membrane has a microporous polymeric film and a polymeric coating on the microporous film, both has an oxygen permeance of at least 775,000 ml/m^2.atm.24hrs (50,000cc/100 $inch^2$.atm.24hrs.and has a CO_2/O_2 permeability ratio (R) of at least 1.5. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show obvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983). The US patent 6376032 either anticipated or strongly suggested the claimed subject matter. It is noted that if the applicant intends to rely on Examples in the specification or in a submitted declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are

commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with the US Patent 6376032.

2. Claims 20-21,23-25,29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6376032. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to have provided the recited pore size and density in the microporous film in the following limitations wherein less than 20% of the pores in the microporous film have a pore size less than 0.014 micron and less than 20% of the pores in the microporous film have a pore size greater than 0.13 micron since Patent No. 6376032 teaches the recited permeability and CO_2/O_2 permeance ratio for use in preserving produce.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1,2,7,8, 11, 13, 15-16, 30 are rejected under 35 U.S.C. 102(b) as being unpatentable by Antoon Jr.(5160768).

Antoon Jr. discloses a gas permeable membrane that comprises a microporous polymeric film comprising a network of interconnected pores such that gases can pass through the film and a polymeric coating on the microporous film (col. 2 lines 43-50).

Antoon Jr. discloses that the polymeric coating membrane has a oxygen permeability (OTR), of at least 775,000 ml/m^2.atm.24hrs (50,000cc/100 $inch^2$.atm.24hrs.) (col. 2 line 52) and has a CO_2/O_2 permeability ratio (R) of at least 1.5 (col. 2 line 54). Antoon Jr. discloses that the microporous membrane can be made of polyethylene or polypropylene (col. 3 lines 54-56). Antoon Jr. discloses a membrane which as an OTR of at least 1,550,000 ml/m^2.atm.24hrs (100,000cc/$inch^2$.atm.24hrs) (col. 2 line 52), and an R ratio of at least 2 (col. 2 line 54). Antoon Jr. discloses a membrane, which has an OTR of at least 2,325,000 ml/m^2.atm.24hrs (150,000cc/100$inch^2$.atm.24hrs) (col. 2 line 52). Antoon Jr. discloses wherein the coating polymer is polydimethyl siloxane (col. 3 lines 35-42). Antoon Jr. discloses that the coating polymer is crosslinked (col. 3 lines 35-42). Antoon Jr. discloses a package which is stored in air and which comprises a seal container, and within the sealed container, a respiring biological material and a packaging atmosphere around the biological material; the sealed container including one or more permeable control sections which provide at least the principal pathway for oxygen and carbon dioxide to enter or leave the packaging atmosphere, at least one of the permeable control section being gas permeable membrane (col. 5 lines 34-35 and col. 6 lines 1-15). Antoon Jr. discloses that the filler is siliceous filler (col. 4 line 63). Since Antoon, Jr. teaches that which appears to be identical to that disclosed by the applicant with respect to permeability, the recited properties not specifically disclosed by Antoon, Jr. would be inherent.

It is the examiner's position that the gas permeable membrane of US patent 5160768 is identical to or only slightly different than the gas permeable membrane

prepared by the method of the claim(s), because both gas permeable membrane has a microporous polymeric film and a polymeric coating on the microporous film, both has an oxygen permeance of at least 775,000 ml/m^2.atm.24hrs (50,000cc/100 $inch^2$.atm.24hrs.and has a CO_2/O_2 permeability ratio (R) of at least 1.5. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show obvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983). It is noted that if the applicant intends to rely on Examples in the specification or in a submitted declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with the US Patent 5160768.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 2-6,20-26,28, 31 rejected under 35 U.S.C. 103(a) as being unpatentable over Antoon Jr. (5160768).

Antoon Jr. discloses a gas permeable membrane that comprises a microporous polymeric film comprising a network of interconnected pores such that gases can pass through the film and a polymeric coating on the microporous film (col. 2 lines 43-50). Antoon Jr. discloses that the polymeric coating membrane has a oxygen permeability (OTR), of at least 775,000 ml/m^2.atm.24hrs (50,000cc/100 $inch^2$.atm.24hrs.) (col. 2 line 52) and has a CO_2/O_2 permeability ratio (R) of at least 1.5 (col. 2 line 54). Antoon Jr. discloses that the microporous membrane can be made of polyethylene or polypropylene (col. 3 lines 54-56). Antoon Jr. discloses a membrane which as an OTR of at least 1,550,000 ml/m^2.atm.24hrs (100,000cc/$inch^2$.atm.24hrs) (col. 2 line 52), and an R ratio of at least 2 (col. 2 line 54). Antoon Jr. discloses a membrane, which has an OTR of at least 2,325,000 ml/m^2.atm.24hrs (150,000cc/100$inch^2$.atm.24hrs) (col. 2 line 52). Antoon Jr. discloses wherein the coating polymer is polydimethyl siloxane (col. 3 lines 35-42). Antoon Jr. discloses that the coating polymer is crosslinked (col. 3 lines 35-42). Antoon Jr. discloses that the microporous polyethylene or polypropylene (col. 3 lines 54-65). Antoon Jr. discloses a package which is stored in air and which comprises a seal container, and within the sealed container, a respiring biological material and a packaging atmosphere around the biological material; the sealed container including one or more permeable control sections which provide at least the principal pathway for oxygen and carbon dioxide to enter or leave the packaging

atmosphere, at least one of the permeable control section being gas permeable membrane (col. 5 lines 34-35 and col. 6 lines 1-15). Antoon Jr. discloses that the microspores polymeric film comprises a polymeric matrix having a siliceous filler dispersed therein (col. 4 line 63).

Antoon Jr. fail to teach a membrane wherein the microporous film comprises a polymeric matrix selected form the group consisting of an essentially linear ultrahigh molecular weight polyethylene having an intrinsic viscosity of at least 18 deciliters/g and an essentially linear ultrahigh molecular weight polypropylene having an intrinsic viscosity of at least 6 deciliters/g. Antoon Jr. fails to teach the recited average pore size and densities of the pores. Since Antoon Jr. teaches a microporous membrane having the recited permeability and CO_2/O_2 permeance ratio for use in preserving produce, as disclosed by the applicant, it would have been obvious to one of ordinary skill in the art to have provided the recited pore size and density in the microporous film. The use of the well known ultra high molecular weight polyethylene and propylene would have been obvious to one having ordinary skill in the art in view of the teaching of the microporous polyolefin membrane to have produced increased strength to the laminate material. Since Antoon, Jr. teaches that which appears to be identical to that disclosed by the applicant with respect to permeability, the recited properties not specifically disclosed by Antoon, Jr. would be inherent.

Declaration

The Clark Declaration filed 12/18/2002 has been considered but is not persuasive.

While applicants use a different process to make their article than that of Antoon Jr., applicant has not provided evidence to show that the articles are structurally different and has not provided evidence to show the criticality of the claimed average pore size. In fact applicant concedes on page 9 of the Declaration that a prior art product has an average pore of less than 0.24 micron which meets the instant claim 1 properties.

Response to Arguments

Applicant's arguments filed 12/6/02 have been fully considered but they are not persuasive.

In response to applicant's argument concerning "polydimethyl siloxane", only instant claims 11 and 26 claim "polydimethyl siloxane" and they were not rejected under double patenting.

In response to applicant's argument that Antoon does not disclose the same process as applicant claims, process limitations are given little or no patentable weight. The method of forming the product is not germane to the issue of patentability of the product itself. Further, when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claim in a product-by-process claim, the burden is on the Applicant to present evidence from which the Examiner could reasonably conclude that the claimed product differs in kind from those of the prior art. *In re Brown*, 459 F.2d 531, 173 USPQ 685 (CCPA 1972); *In re Fessman*, 489 F.2d 742, 180 USPQ 324 (CCPA 1974). This burden is NOT discharged

solely because the product was derived from a process not known to the prior art. *In re Fessman*, 489 F.2d 742, 180 USPQ 324 (CCPA 1974).

Furthermore, the determination of patentability for a product-by-process claim is based on the product itself and not on the method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 946, 966 (Fed. Cir. 1985) and MPEP §2113. In this case, the limitation of preparing a uniform mixture comprising a polymeric matrix material in the form of a powder, a finely divided particulate substantially water insoluble filler and a processing oil, extruding the mixture as a continuous sheet, forwarding the continuous sheet without drawing to a pair of heated calendar rolls, passing the continuous sheet through the calendar rolls to form a sheet of lesser thickness, passing the sheet from step D to a first extraction zone in which the processing oil is substantially removed by extraction zone in which the processing oil is substantially removed by extraction with an organic extraction liquid which is a good solvent for the processing oil, a poor solvent for the polymeric matrix material, and more volatile than the processing oil, passing the sheet from step E to a second extraction zone in which the organic extraction liquid is substantially removed by steam or water or both and passing the sheet from step F through a forced air dryer to remove residual water and organic extraction is a method of production and therefore does not determine the patentability of the product itself.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane J Rhee whose telephone number is 703-605-4959. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 703-308-4251. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Janerhee

Janerhee
3/17/03

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

3/24/03